UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

REGENLAB USA LLC, Plaintiff, v. RAJ KANODIA, M.D., GARDEN CITY DERMATOLOGY, P.C., TRIFECTA HEALTH MEDICAL P.C., JANE OR JOHN DOE Defendants.	Civil Action No. 1:17-cv-03845 COMPLAINT **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff RegenLab USA LLC ("RegenLab" or "Plaintiff") brings this action against Defendants Raj Kanodia, M.D. ("Kanodia"), Garden City Dermatology, P.C. ("Garden City"), Trifecta Health Medical P.C. ("Trifecta"), and Jane or John Doe ("Doe") (collectively, "Defendants") and alleges as follows:

STATEMENT OF THE CASE

1. This is an action for patent infringement in violation of the Patent Laws of the United States, 35 U.S.C. § 271 *et seq*., and for injunctive relief and damages under 35 U.S.C. §§ 283 – 285, arising from Defendants' unauthorized use of RegenLab's patented technology in connection with Defendants' using, actively inducing others to use, offering to sell, and/or selling infringing products.

2. RegenLab brings this action to protect its reputation as an innovator, retain control over its intellectual property, prevent its technology from being unlawfully exploited by others, and to avoid irretrievably lost sales.

3. RegenLab hereby seeks: (1) injunctive relief against Defendants' continued unauthorized, improper and willful commercial use and exploitation of its patented technology; and (2) all damages arising from Defendants' past and present infringement, including all statutory damages, and RegenLab's attorneys' fees and costs for having to bring this suit to enforce its rights.

PARTIES

4. RegenLab is a Limited Liability Company organized and existing under the laws of Delaware and having a place of business at 575 Madison Avenue, New York, NY 10022-2511.

5. RegenLab is an affiliate of Regen Lab SA, a corporation organized and existing under the laws of Switzerland and having a place of business at En Budron B2, 1052 Le Mont-sur-Lausanne, Switzerland. RegenLab, along with Regen Lab SA, is known throughout the world as a technology innovator and provider of medical and pharmaceutical products, which are distributed under the famous REGENLAB® brand. REGENLAB® and the products sold under this brand are known worldwide to be synonymous with superior technology and quality.

6. Upon information and belief, Kanodia is a corporation organized and existing under the laws of the State of California and having a place of business at 521 Park Avenue, New York, NY 10065.

7. Upon information and belief, Kanodia is a distributor of medical and pharmaceutical products, including the infringing products at issue in this litigation.

8. Upon information and belief, Garden City is a corporation organized and existing under the laws of the State of New York and having a place of business at 901 Stewart Avenue, Garden City, NY 11530.

9. Upon information and belief, Garden City is a distributor of medical and pharmaceutical products, including the infringing products at issue in this litigation.

10. Upon information and belief, Trifecta is a corporation organized and existing under the laws of the State of New York and having a place of business at 115 Broadway, New York, NY 10006.

11. Upon information and belief, Trifecta is a distributor of medical and pharmaceutical products, including the infringing products at issue in this litigation.

12. Upon information and belief, Jane or John Doe are additional distributors of medical and pharmaceutical products, including the infringing products at issue in this litigation. RegenLab may seek to add them to this Complaint as they are identified.

JURISDICTION AND VENUE

13. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.

14. Defendants have been doing business in this District, and have and are advertising, distributing, offering for sale, selling, and using products that infringe RegenLab's patent rights to persons located within this District.

15. Kanodia markets infringing products through physical sales at its place of business in New York. Kanodia also markets infringing products through operation of an interactive website, available at www.drkanodia.com, which is publicly accessible to consumers in New York and throughout the U.S.

16. Garden City markets infringing products through physical sales at its place of

business in New York. Garden City also markets infringing products through operation of an interactive website, available at www.gardencityderm.com, which is publicly accessible to consumers in New York and throughout the U.S.

17. Trifecta markets infringing products through physical sales at its place of business in New York. Trifecta also markets infrining products through operation of an interactive website, available at www.trifectamedspanyc.com, which is publicly accessible to consumers in New York and throughout the U.S.

18. This Court has personal jurisdiction over Defendants because, *inter alia*, Defendants: (1) transact business within this District; (2) contract to supply goods or services in this District; (3) have committed a tortious act within this District; (4) have committed a tortious act causing injury to RegenLab within this District; (5) regularly do or solicit business, or engage in other persistent course of conduct, or derive substantial revenue from goods used or consumed or services rendered, in this District; (6) expect or should reasonably expect their acts to have consequences in this District and derive substantial revenue from interstate or international commerce; (7) have systematic and continuous contacts with this District; (8) continue to transact and do business in this District; and (9) have websites and social media accounts that are accessible in this District.

19. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c) and/or 1400(b). A substantial part of the wrongful events giving rise to this action took place in this District and RegenLab has suffered harm in this District.

FACTS COMMON TO ALL CLAIMS FOR RELIEF

Background

20. RegenLab alleges that a product sold under the brand "Eclipse PRP" infringes its

patent rights. Estar Technologies Ltd. ("Estar") is the manufacturer of this product, which Estar markets under various other brand names.

21. Upon information and belief, Estar began developing infringing products to compete with RegenLab's own products in 2006.

22. On or about June 2009, Regen Lab SA met with Estar and informed Estar that its products infringe its patent rights. Despite this, Estar has continued to promote and sell infringing products, including those at issue in this litigation.

23. The Eclipse PRP product is distributed by Eclipse Aesthetics LLC ("Eclipse"). Upon information and belief, Eclipse sells the Eclipse PRP product to Defendants, who then resell the Eclipse PRP product to their respective customers.

24. Before Eclipse was a distributor for Estar, it was RegenLab's U.S. distributor. The January 2011 distribution agreement between RegenLab and Eclipse acknowledges RegenLab's patent rights. Despite this, Eclipse has continued to promote and sell infringing products, including those at issue in this litigation.

25. In April 2013, the U.S. Food and Drug Administration ("FDA") issued a cease and desist letter to Eclipse for "off label" promotion which could significantly affect safety and/or effectiveness. Shortly thereafter, Regen Lab SA terminated the distribution agreement with Eclipse due to Eclipse's serious breaches of U.S. regulations.

26. Following termination of the distribution agreement between Regen Lab SA and Eclipse, Regen Lab SA formed RegenLab USA LLC (Plaintiff) to market and distribute its products in the U.S.

27. In or about June 2013, Eclipse started selling the Eclipse PRP product in the U.S. This was less than two months after termination of the distribution agreement between Regen

Lab SA and Eclipse.

28. Upon information and belief, Estar and/or Eclipse copied RegenLab's products that incorporate the technology of the patent at issue to develop the Eclipse PRP product. RegenLab has filed suit against Estar and Eclipse for patent infringement, Case No. 16-cv-08771 (ALC) (S.D.N.Y.).

29. Termination of the distribution agreement between Regen Lab SA and Eclipse caused severe disruption to Regen Lab SA's sales activities in the U.S. As a consequence, RegenLab's sales in the U.S. suffered. RegenLab had and still has difficulties contacting customers who purchased its products through Eclipse. In addition, Eclipse now directly competes with RegenLab as it sells and promotes infringing products.

30. In March 2014, Eclipse hired former employees of RegenLab. Upon information and belief, Eclipse hired these employees because of their strategic positions within RegenLab, which gave them knowledge of RegenLab's confidential information, including customer lists, technical processes, product and marketing strategies, and business processes. On information and belief, Estar and/or Eclipse have and continue to exploit RegenLab's confidential information obtained from these employees to the detriment of RegenLab.

31. Eclipse has continued to unlawfully promote products for "off label" uses. In October 2015, the FDA issued a cease and desist letter to Eclipse for its "off label" promotion of the Eclipse PRP product. The FDA letter states that Eclipse does not have "an approved application for premarket approval," its product is "misbranded," promotion has been "false and misleading," and that Eclipse should "immediately cease promoting Eclipse PRP™ for unapproved uses." In March 2016, the FDA issued still another cease and desist letter to Eclipse, this time for its "MicroPen" that is used in combination with platelet rich plasma products. The

FDA letter states that Eclipse does "not have an approved application for premarket approval," its product is "misbranded," there are "safety concerns," and that Eclipse should "immediately cease activities."

The '957 Patent and RegenLab's Products

32. RegenLab is the exclusive licensee of U.S. Pat. No. 8,529,957 ("the '957 patent"), entitled "Cell preparations for extemporaneous use, useful for healing and rejuvenation in vivo," which was duly and legally issued by the United States Patent and Trademark Office on September 10, 2013. RegenLab's license includes all substantial rights under the '957 patent, including the right to sue in its own name and collect damages for any past, present, and future infringement.

33. The '957 patent claims priority to international application No. PCT/EP2007/058695, which was filed on August 21, 2007, which in turn claims priority to international application No. PCT/EP2006/065493, which was filed on August 21, 2006.

34. A number of continuation applications claim priority to the '957 patent. For example, U.S. App. No. 15/044,498 is currently pending before the U.S. Patent Office. This published on June 9, 2016 as U.S. Pub. 2016/0158286. U.S. App. No. 15/369,966 is also currently pending before the U.S. Patent Office. This published on June 9, 2016 as U.S. Pub. 2017/0080028.

35. RegenLab distributes products for preparing platelet rich plasma from a patient's own blood, including its RegenKit® products. The RegenKit® products are marked with the '957 patent in accordance with 35 U.S.C. § 287.

COUNT I
Infringement of the '957 Patent

36. RegenLab repeats and re-alleges each and every allegation in the foregoing paragraphs as if fully set forth herein.

37. Defendants are not authorized by RegenLab to use the technology of the '957 patent.

38. Upon information and belief, Defendants have been and still are actively inducing others to infringe one or more claims of the '957 patent under 35 U.S.C. § 271(b) through the sale, promotion, and/or instruction for use of infringing products. Upon information and belief, Defendants' sale, promotion, and/or instruction for use of infringing products have been and are made with the specific intent that those products be used to infringe the '957 patent.

39. The Eclipse PRP product is regulated by the FDA. The Eclipse PRP product is packaged with instructions for use in accordance with FDA requirements. Use of the Eclipse PRP product in accordance with those instructions infringes the '957 patent.

40. Upon information and belief, Defendants induce their customers to infringe the '957 patent when they sell and offer to sell the Eclipse PRP product. Upon information and belief, Defendants instruct their customers to use the Eclipse PRP product in an infringing way. This includes instructing customers to use the Eclipse PRP product in accordance with its packaged instructions.

41. Upon information and belief, Defendants have been and still are contributing to the infringement of one or more claims of the '957 patent by others under 35 U.S.C. § 271(c) through the sale, promotion, and/or instruction for use of infringing products. Upon information and belief, the infringing products are material to practicing the invention of the '957 patent, have no substantial non-infringing uses, and are known to Defendants to be especially made or especially adapted for use in infringing the '957 patent.

42. Upon information and belief, Defendants contribute to infringement of the '957 patent when they sell and offer to sell the Eclipse PRP product to their customers. Upon

information and belief, Defendants know the Eclipse PRP product to be especially made or especially adapted for use in infringing the '957 patent, and that the Eclipse PRP product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

43. Upon information and belief, Defendants have been and still are directly infringing one or more claims of the '957 patent under 35 U.S.C. § 271(a) by using, selling, and/or offering for sale infringing products without the authorization of RegenLab.

44. Upon information and belief, Defendants' infringement occurs in New York. This includes Defendants' use, offer to sell, and selling of the Eclipse PRP product at their respective physical locations in New York.

45. Kanodia advertises the Eclipse PRP product on its website (www.drkanodia.com). Kanodia also has a video posted on its website. The video induces customers to infringe by instructing them to use the Eclipse PRP product in an infringing way, as well as shows Kanodia's own use of the Eclipse PRP product in an infringing way.

46. Upon information and belief, Kanodia directly infringes the '957 patent at its location in New York by using the Eclipse PRP product in an infringing way. Upon information and belief, Kanodia offers a number of cosmetic treatments, some advertised on its website, which include using the Eclipse PRP product in an infringing way.

47. Garden City advertises the Eclipse PRP product on its website (www.gardencityderm.com). The website offers the Eclipse PRP product for sale at an "UNBEATABLE PRICE!"

48. Upon information and belief, Garden City directly infringes the '957 patent at its location in New York by using the Eclipse PRP product in an infringing way. Upon information

and belief, Garden City offers a number of cosmetic treatments, some advertised on its website, which include using the Eclipse PRP product in an infringing way.

49. Trifecta advertises the Eclipse PRP product on its website (www.trifectamedspanyc.com). Trifecta also has a video posted on its website. The video induces customers to infringe by instructing them to use the Eclipse PRP product in an infringing way, as well as shows Trifecta's own use of the Eclipse PRP product in an infringing way.

50. Upon information and belief, Trifecta directly infringes the '957 patent at its location in New York by using the Eclipse PRP product in an infringing way. Upon information and belief, Trifecta offers a number of cosmetic treatments, some advertised on its website, which include using the Eclipse PRP product in an infringing way.

51. Upon information and belief, Defendants' activities are directly related to the commercial development, sale, and/or distribution of infringing products. In particular, the advertising of the Eclipse PRP product and instructional videos are for commercial development, sale, and/or distribution.

52. With regard to representative claim 20 of the '957 patent, on information and belief, the Eclipse PRP product is used to prepare a cell composition. On information and belief, the Eclipse PRP product is used to centrifuge whole blood in a separator tube selected from: a glass separator tube containing a polyester-based thixotropic gel and a buffered sodium citrate solution at 0.10 M; or a polyethylene terephthalate separator tube containing a thixotropic gel formed by a polymer mixture and an anhydrous sodium citrate at 3.5 mg/mL. On information and belief, the Eclipse PRP product is used to centrifuge at a force of about 1500 g up to about 2000 g for a sufficient length of time to form a barrier between full plasma containing platelets, lymphocytes and monocytes and a pellet containing the erythrocytes. On information and belief, the Eclipse PRP

product is used to optionally separate enriched platelet rich plasma from full plasma by removing about half of the supernatant formed during the centrifuging step, said removed supernatant containing platelet poor plasma, wherein the separation is made by collecting the supernatant from atop of said barrier; and wherein the enriched plasma is enriched in leucocytes, thrombocytes and adhesion proteins as compared to native whole blood. On information and belief, the Eclipse PRP product is used to re-suspend the enriched platelet rich plasma or the full plasma to form a platelet concentrate. On information and belief, the Eclipse PRP product is used to provide a cell extract comprising cells selected from the group consisting of adipocytes; adipose stem cells; fat cells; corneal cells; corneal limbal stem cells; cornea keratinocytes; dermal cells; fibroblasts; melanocytes; Langerhan's cells; bone marrow cells; muscle cells; satellite stem cells; myoblast progenitor stem cells; osteoblasts; chondrocytes; periosteal membrane cells; umbilical cord stem cells; stem cells; Schwann cells; cartilage cells; ligament cells; tendon cells; connective tissue cells, gingival cells and pancreas islet cells. On information and belief, the Eclipse PRP product is used to admix the platelet concentrate with the cell extract.

53. Estar and/or Eclipse have had notice of the ‘957 patent since it issued on September 10, 2013.

54. Defendants are jointly and severally liable with Estar and/or Eclipse for infringement of the ‘957 patent.

55. Defendants’ infringement continues in willful disregard of RegenLab’s rights, making this case exceptional under 35 U.S.C. § 285.

56. Upon information and belief, Defendants have not been indemnified for their infringement.

57. These allegations are based on RegenLab's current understanding of Defendants' products and RegenLab reserves the right to amend them as more information becomes available.

58. RegenLab has suffered and continues to suffer damage from loss of sales and customers in New York and throughout the U.S. by Defendants' infringement of the '957 patent, and claims all damages to which it is entitled, including but not limited to lost sales and profits and reasonable royalties.

59. The harm to RegenLab resulting from the infringing acts of Defendants is irreparable, continuing, not fully compensable by money damages, and will continue unless permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. That judgment be entered in favor of Plaintiff and against Defendants on each and every Claim in this Complaint;

B. That Defendants be adjudicated and decreed to have infringed, contributed to the infringement of, and/or induced the infringement of the '957 patent;

C. That a permanent injunction be entered against Defendants, their officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with Defendants who receive actual notice of the injunction by personal service or otherwise, from any further infringement of the '957 patent pursuant to 35 U.S.C. § 283;

D. That Plaintiff be awarded its damages, suffered by reason of the infringements by Defendants, together with prejudgment interest;

E. That the damages awarded to Plaintiff be trebled pursuant to 35 U.S.C. § 284 due to the willful acts of infringement complained of herein;

F. That this be declared an exceptional case pursuant to 35 U.S.C. § 285;

G. That Plaintiff be awarded its attorneys' fees and costs; and

H. That Plaintiff be awarded any other and further relief that this Court may deem just and proper or otherwise permitted by law.

JURY DEMAND

Plaintiff demands a trial by jury on all claims and issues so triable.

Respectfully Submitted,

Date: May 22, 2017

/s/ Stephen Ball

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